Original Article

Rapid deployment versus its conventional counterpart in aortic valve replacement: comparison of early hemodynamic outcomes

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Background: Edwards Intuity is designed for rapid deployment based on the structure of Magna Ease. This study was conducted to compare early hemodynamic performance between the two valves.

Methods: Patients who underwent aortic valve replacement (AVR) using Edwards Intuity or Carpentier-Edwards PERIMOUNT Magna Ease in our institution from June 2016 to July 2021 were enrolled. Intuity valve was used in 215 patients, and Magna Ease valve was used in 198 patients, respectively. Early postoperative echocardiographic data were available in 99.0% (409/413) of the patients. The transvalvular mean pressure gradient, effective orifice area, and effective orifice area index were compared between the valves stratified by prosthesis size.

Results: There were no differences in the proportion of female patients or body surface area between the groups. Mean pressure gradient on early postoperative echocardiography was significantly lower in Intuity valve than Magna Ease valve for 19, 21, 23, and 25 mm valves (15.5±5.0 *vs.* 20.8±9.1 mmHg, P=0.004; 12.7±4.2 *vs.* 15.6±5.3 mmHg, P=0.001; 11.5±3.3 *vs.* 13.4±5.8 mmHg, P=0.034; and 9.9±3.1 *vs.* 12.3±4.0 mmHg, P=0.029; respectively). Effective orifice area was larger in Intuity valve than Magna Ease valve for 19 mm valve (1.45±0.38 *vs.* 1.19±0.28 cm^2, P=0.002), and effective orifice area index was also larger in Intuity valve than Magna Ease valve for 19 mm valve (0.96±0.26 *vs.* 0.80±0.20 cm^2/m^2, P=0.005). Early clinical outcomes, including operative mortality and postoperative complications, demonstrated no significant differences between the groups.

Conclusions: Edwards Intuity demonstrated superior early hemodynamic performance compared with Magna Ease in a size-by-size comparison, and this superiority was more definite for small prostheses.

Keywords: Aortic valve replacement (AVR); bioprosthetic valve; rapid deployment valve; hemodynamics

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Introduction

The introduction of a rapid-deployment (RD) valve into clinical practice has expanded the already rich portfolio of aortic valve substitutes for patients undergoing aortic valve replacement (AVR). Both European and American trials (TRITON and TRANSFORM trials) (1,2) and many consecutive studies demonstrated excellent clinical outcomes after AVR using a RD valve.

RD valves are known to have several advantages compared with conventional bioprostheses. It allows for a shorter aortic cross-clamp time (2,3), thus shortening the overall procedural time. It also simplifies and facilitates minimally invasive AVR. Furthermore, the hemodynamic performance of RD valves are reported to be better than that of conventional bioprostheses (4,5).

Edwards Intuity (Edwards Lifesciences, Irvine, California, USA) is a rapid-deployment prosthesis that is constructed on the platform of the Carpentier-Edwards PERIMOUNT Magna Ease (Edwards Lifesciences, Irvine, CA, USA) and incorporates a balloon expandable, stainless-steel cloth-covered inflow frame for a subannular fixation system. Magna Ease valve/prosthesis is a bovine, stented, supra-annular aortic valve bioprosthesis based on the designs of the well-established PERIMOUNT and Magna valves with proven long-term durability (6).

Although the Intuity valve has been shown to perform well in many studies (1,7,8), few studies have explored size-by-size comparisons of the hemodynamic performance of this valve to its conventional counterpart, Magna Ease valve. Because these two valves are based on identical functional components except for the subvalvular stent frame, the comparison of these two valves can preclude any confounding factors originating from different prosthetic materials and valve construction, and enable us to focus only on the effect of the subvalvular system on valve hemodynamics.

The aim of this study was to compare the early hemodynamic profile of the Intuity valve with that of the Magna Ease valve stratified by prosthesis size. We present this article in accordance with the STROBE reporting checklist (available at https://jtd.amegroups.com/article/view/10.21037/jtd-23-318/rc).

Highlight box

Key findings

- Edwards Intuity showed superior early hemodynamic performance compared with PERIMOUNT Magna Ease in a size-by-size comparison.

What is known and what is new?

- There have been many comparative studies reporting that Intuity valve demonstrated superior hemodynamics compared with conventional bioprosthetic valves
- The present study is the first study that directly compared the hemodynamics between Intuity valve and its conventional counterpart, Magna Ease valve, as a control prosthesis in a size-by-size fashion.

What is the implication, and what should change now?

- Superior hemodynamics with comparable clinical outcomes of Intuity over Magna Ease may help guide device selection in small aortic roots.

Methods

Study population

The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by Institutional Review Board of Seoul National University Hospital (No. H-2109-010-1251) and individual consent for this retrospective analysis was waived.

Of 780 patients who underwent aortic valve surgery between June 2016 and July 2021 in our institution, AVR was performed in 768 patients, and AVR using a bioprosthetic valve was performed in 551 patients. Among these patients, 215 patients who received Edwards Intuity for aortic valve substitute and 198 patients who received Carpentier-Edwards PERIMOUNT Magna Ease valve for aortic valve substitute were enrolled in this study (*Figure 1*). Both Intuity valve and Magna Ease valve were introduced to our center around the same time, and each valve was regularly used during the study period.

Surgical techniques and strategy

The surgical procedures and strategies of RDAVR have been illustrated in previous study (9). All operations were conducted under median sternotomy. Cardiopulmonary bypass with mild or moderate hypothermia and cardioplegic arrest was also used in all patients. After aortotomy, aortic valve excision, and annular decalcification were performed, the valve replica was always simulated to the annulus; we found that the semilunar design of the replica does not perfectly fit to the native annulus in many cases (actually in all cases of bicuspid valves). We focused

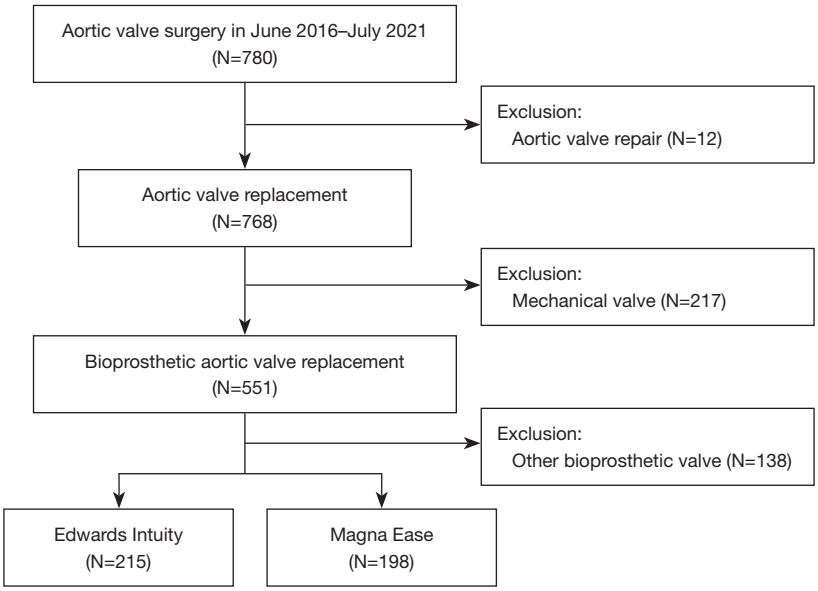

Figure 1 Flow diagram of patient enrollment.

on these discrepancies; 3 guiding sutures and several additional sutures, which was our modification of the original manufacturer's instructions for use, were placed at the surgeon's discretion after careful inspection of the annular geometry to prevent incomplete fitting after valve deployment. After parachuting the valve into the annulus, the delivery system was temporarily removed from the valve holder. Then, a 5-mm videoscope was inserted through the central hole of the holder for evaluation of the fit from the inside. The position of the valve at the left ventricular outflow tract (LVOT), spatial relationship with the anterior leaflet of the mitral valve, and any loosening or displacement of the guiding sutures were carefully examined under direct vision. After the delivery system was reassembled, balloon expansion was performed with 4.5 or 5.0 atm for 10 seconds, following the instructions. After balloon expansion, the videoscope was reinserted, and checked for adequate subannular expansion, accurate prosthesis position, and any related abnormalities. After confirmation, the guiding sutures were tied, and the aortotomy was closed using a typical double-layer technique (or replaced with a graft in cases of concomitant ascending aorta replacement).

In cases of AVR with conventional stented bioprostheses, operations were performed under median sternotomy or upper partial sternotomy. After the excision of diseased AV, the annulus was prepared for placing the prosthesis, the valve size was selected, and the prosthesis was implanted. In most patients, non-everting mattress sutures which were buttress-reinforced with polytetrafluoroethylene as a tubule were used. Everting or non-everting mattress sutures with polytetrafluoroethylene as a usual pledget, instead of a tubule, were occasionally used as needed. Continuous suture technique was used in 11 patients (5.1%). Knot-tying was performed manually or with an automated knot-fastener.

Prosthesis selection between Intuity valve and other bioprostheses including Magna Ease valve was largely determined by the surgeon's preference. Intuity valve was used exclusively by a single surgeon, whereas Magna Ease valve was used by all surgeons in our institution.

Evaluation of early clinical outcomes

Operative mortality was defined as any death within 30 days. Continuous electrocardiography monitoring was applied to all patients until discharge, and the detection of any short runs of atrial fibrillation was regarded as an occurrence of postoperative atrial fibrillation. Low cardiac output was defined as a cardiac index <2.0 L/min/m^2, a systolic arterial pressure <90 mmHg requiring inotropic support (dopamine or dobutamine) of >5 mg/kg/min or a mechanical circulatory support (e.g., intra-aortic balloon pump). Acute kidney injury was defined as a two-fold increase in serum creatinine level from the preoperative value, glomerular filtration rate decrease by 50%, urine output <0.5 mL/kg/h for 12 hours or a need for renal replacement therapy regardless of serum creatinine level.

Respiratory complications included prolonged mechanical ventilation over 48 hours postoperatively, pneumonia, or the need for tracheostomy.

Evaluation of early hemodynamic outcomes

Early postoperative echocardiography was performed in 99.0% (409 out of 413) of the study patients at median 6 days (interquartile range, 5–7) after surgery, except for a few mortality cases. The echocardiographic parameters of the prostheses included the transvalvular mean pressure gradient (PG) and effective orifice area (EOA). The measurements of the parameters were performed according to the recommendations for the imaging assessment of prosthetic heart valves (10). Transvalvular mean PG, EOA, and EOA index (EOAI) were compared between the groups stratified by prosthesis size.

Statistical analysis

Statistical analysis was performed using SPSS statistics software version 25.0 (IBM Inc., Armonk, New York, USA), and SAS software, version 9.4 (SAS Institute, Cary, North Carolina, USA). Continuous variables are presented as mean ± standard deviation for normally distributed data or median with interquartile range for not normally-distributed data. Categorical variables are presented as the number and percentage of the subjects. Comparisons of baseline characteristics, operative data, early clinical outcomes, and early hemodynamic outcomes were performed using the chi-square test or Fisher's exact test for categorical variables, and Student's *t*-test or Mann-Whitney test for continuous variables, as appropriate. All tests were two-tailed, and a P value <0.05 was considered statistically significant.

Results

Preoperative characteristics

There was no difference in the proportion of female, body mass index, or body surface area between the groups, but the patients who received Magna Ease valve were older than those who received Intuity valve (68.6±10.5 *vs.* 71.9±9.2 years old in Intuity *vs.* Magna Ease, P=0.001). Risk factors showed no significant difference between the groups, except for chronic kidney disease (20.5% *vs.* 28.8% in Intuity *vs.* Magna Ease, P=0.049) and reoperation (6.0% *vs.* 12.1% in Intuity *vs.* Magna Ease, P=0.031) (*Table 1*).

Operative data

A prosthesis size of 21 mm was the most frequently implanted in both groups (29.3% and 39.9% in Intuity and Magna Ease valves, respectively), followed by 23 mm (23.7% and 31.8% in Intuity and Magna Ease valves, respectively).

Isolated AVR was performed in 32.6% and 56.6% of the Intuity and Magna Ease groups, respectively (P<0.001). In the overall population, concomitant procedures included mitral valve surgery (16.9%), tricuspid valve surgery (6.3%), coronary artery bypass grafting (8.7%), arrhythmia surgery (8.2%), and aorta surgery (27.6%). Concomitant procedures were more frequently performed in the Intuity group (67.4% *vs.* 43.4%, P<0.001), especially mitral valve surgery (22.3% *vs.* 11.1%, P<0.001) and aorta surgery (42.3% *vs.* 11.6%, P<0.001) (*Table 2*).

Early clinical outcomes

Operative mortality was 1.7% (7 out of 413), and there was no significant difference between the groups. Common postoperative complications included postoperative atrial fibrillation (39.2%), acute kidney injury (10.9%), and respiratory complications (12.8%). There were no significant differences in the incidences of postoperative complications including permanent pacemaker implantation (1.4% *vs.* 1.0% in Intuity *vs.* Magna Ease, P>0.999) between the 2 groups (*Table 3*).

Early hemodynamic outcomes

Transvalvular mean PG in the overall population was significantly lower in Intuity valve than in Magna Ease valve (12.0±4.3 *vs.* 15.3±6.8 mmHg, P<0.001). When stratified by prosthesis size, transvalvular mean PGs were also significantly lower in Intuity valve with 19 mm (15.5±5.0 *vs.* 20.8±9.1 mmHg, P=0.004), 21 mm (12.7±4.2 *vs.* 15.6±5.3 mmHg, P=0.001), 23 mm (11.5±3.3 *vs.* 13.4±5.8 mmHg, P=0.034) and 25 mm (9.9±3.1 *vs.* 12.3±4.0 mmHg, P=0.029) prostheses, but not the 27 mm prosthesis.

EOA in the overall population was significantly larger in Intuity valve than in Magna Ease valve (1.73±0.52 *vs.* 1.53±0.41 cm^2, P<0.001). When stratified by prosthesis size, no significant differences of EOAs were found between the groups in patients with 21, 23, 25 and 27 mm prostheses. However, in patients with 19 mm prostheses, the EOA was

Table 1 Preoperative demographics and risk factors for the study population

Variable	Intuity (n=215)	Magna Ease (n=198)	P value
Sex (female), n (%)	93 (43.3)	89 (44.9)	0.729
Age, years	68.6±10.5	71.9±9.2	0.001
Body mass index, kg/m^2	24.2±3.4	24.0±3.5	0.541
Body surface area, m^2	1.67±0.19	1.65±0.18	0.233
Risk factors, n (%)			
Diabetes mellitus	51 (23.7)	60 (30.3)	0.132
Hypertension	124 (57.7)	128 (64.6)	0.147
Dyslipidemia	93 (43.3)	77 (38.9)	0.368
COPD	18 (8.4)	11 (5.6)	0.263
Stroke	23 (10.7)	23 (11.6)	0.767
Chronic kidney disease	44 (20.5)	57 (28.8)	0.049
Renal replacement therapy	8 (3.7)	9 (4.5)	0.673
Coronary artery disease	49 (22.8)	45 (22.7)	0.988
PAOD	12 (5.6)	13 (6.6)	0.675
Infective endocarditis	3 (1.4)	10 (5.1)	0.046
Atrial fibrillation	25 (11.6)	26 (13.1)	0.643
Reoperation	13 (6.0)	24 (12.1)	0.031
EuroSCORE II	3.09±4.53	3.17±3.40	0.836
NYHA class, n (%)			0.646
I	51 (23.7)	37 (18.7)	
II	121 (56.3)	121 (61.1)	
III	36 (16.7)	33 (16.7)	
IV	7 (3.3)	7 (3.5)	
Etiology, n (%)			
Degenerative	70 (32.6)	94 (47.5)	0.002
Bicuspid	113 (52.6)	60 (30.3)	<0.001
Rheumatic	8 (3.7)	10 (5.1)	0.509
Infectious	3 (1.4)	9 (4.5)	0.078
Prosthetic valve failure	1 (0.5)	5 (2.5)	0.109
Pure aortic regurgitation	20 (9.3)	20 (10.1)	0.784
Emergency operation, n (%)	4 (1.9)	4 (2.0)	>0.999

Continuous variables are presented as mean ± standard deviation. COPD, chronic obstructive pulmonary disease; EuroSCORE, European System for Cardiac Operative Risk Evaluation, NYHA, New York Heart Association; PAOD, peripheral arterial occlusive disease.

Table 2 Operative data

Variable	Intuity (n=215)	Magna Ease (n=198)	P value
Valve size, n (%)			–
19 mm	35 (16.3)	36 (18.2)	
21 mm	63 (29.3)	79 (39.9)	
23 mm	51 (23.7)	63 (31.8)	
25 mm	44 (20.5)	13 (6.6)	
27 mm	22 (10.2)	7 (3.5)	
Isolated AVR, n (%)	70 (32.6)	112 (56.6)	<0.001
Concomitant procedures, n (%)	145 (67.4)	86 (43.4)	<0.001
Mitral valve surgery	48 (22.3)	22 (11.1)	0.002
Tricuspid valve surgery	15 (7.0)	11 (5.6)	0.552
CABG	9 (4.2)	27 (13.6)	0.001
Arrhythmia surgery	15 (7.0)	19 (9.6)	0.333
Aorta surgery	91 (42.3)	23 (11.6)	<0.001
Procedural times			
CPB time, min	166 (145, 202)	139 (105, 193)	<0.001
ACC time, min	113 (96, 138)	87 (71, 121)	<0.001

Continuous variables are presented as medians with interquartile ranges. AVR, aortic valve replacement; CABG, coronary artery bypass grafting; CPB, cardiopulmonary bypass; ACC, aortic cross-clamp.

Table 3 Early clinical outcomes

Variable	Intuity (n=215)	Magna Ease (n=198)	P value
Operative mortality, n (%)	6 (2.8)	1 (0.5)	0.124
Postoperative complication, n (%)			
Postoperative atrial fibrillation	86 (40.0)	76 (38.4)	0.737
Low cardiac output	8 (3.7)	5 (2.5)	0.579
Permanent pacemaker implantation	3 (1.4)	2 (1.0)	>0.999
Acute kidney injury	27 (12.6)	28 (14.1)	0.636
Bleeding reoperation	7 (3.3)	7 (3.5)	0.875
Stroke	7 (3.3)	3 (1.5)	0.342
Respiratory complication	24 (11.2)	27 (13.6)	0.445
Mediastinitis	3 (1.4)	1 (0.5)	0.624
Infective endocarditis	0 (0.0)	0 (0.0)	–

Table 4 Comparison of early hemodynamic performance between the groups

Variable	Intuity		Magna Ease		P value
	n	Mean ± SD	n	Mean ± SD	
Mean PG (mmHg)					
19 mm	35	15.5±5.0	35	20.8±9.1	0.004
21 mm	62	12.7±4.2	79	15.6±5.3	0.001
23 mm	51	11.5±3.3	63	13.4±5.8	0.034
25 mm	42	9.9±3.1	13	12.3±4.0	0.029
27 mm	22	9.0±2.8	7	8.6±4.1	0.767
Overall	212	12.0±4.3	197	15.3±6.8	<0.001
EOA (cm^2)					
19 mm	35	1.45±0.38	35	1.19±0.28	0.002
21 mm	61	1.55±0.38	79	1.51±0.32	0.474
23 mm	49	1.68±0.33	63	1.63±0.36	0.469
25 mm	42	2.03±0.56	13	1.97±0.60	0.634
27 mm	22	2.22±0.72	7	1.90±0.43	0.328
Overall	209	1.73±0.52	197	1.53±0.41	<0.001
EOA index (cm^2/m^2)					
19 mm	35	0.96±0.26	35	0.80±0.20	0.005
21 mm	61	0.98±0.25	79	0.94±0.22	0.601
23 mm	49	1.00±0.22	63	0.94±0.20	0.259
25 mm	42	1.13±0.31	13	1.16±0.39	0.782
27 mm	22	1.25±0.44	7	1.02±0.24	0.206
Overall	209	1.04±0.30	197	0.93±0.24	<0.001

SD, standard deviation; PG, pressure gradient; EOA, effective orifice area.

significantly larger in Intuity valve than in Magna Ease valve (1.45±0.38 *vs.* 1.19±0.2 cm^2, P=0.002).

EOAI demonstrated similar results to EOA that it was significantly larger in Intuity valve than in Magna Ease valve only with 19 mm prosthesis (0.96±0.26 *vs.* 0.80±0.20 cm^2/m^2, P=0.005) (*Table 4* and *Figure 2*).

Dimensionless parameter [Doppler velocity index (DVI)] and LVOT hemodynamic parameters [LVOT velocity time integral (VTI) and peak velocity] also demonstrated significant differences between the groups in the overall population. When stratified by prosthesis size, a trend of superior hemodynamics was observed in Intuity valve, although it failed to prove statistical significance in some subgroups of patients (Table S1).

Discussion

The present study demonstrated 3 main findings. First, the early hemodynamic performances of Edwards Intuity were superior to those of Carpentier-Edwards PERIMOUNT Magna Ease for all prosthesis sizes. Second, this superior hemodynamic performance of Intuity valve was more prominent in the smaller prostheses. Third, there were no differences between Intuity and Magna Ease valves in the early clinical outcomes after AVR, including the need for permanent pacemaker implantation (*Figure 3*).

The excellent hemodynamics of RD valve has been reported in previous observational and prospective studies (1,2,7,11). Comparative studies of RD valve versus conventional bioprosthetic valves have also consistently

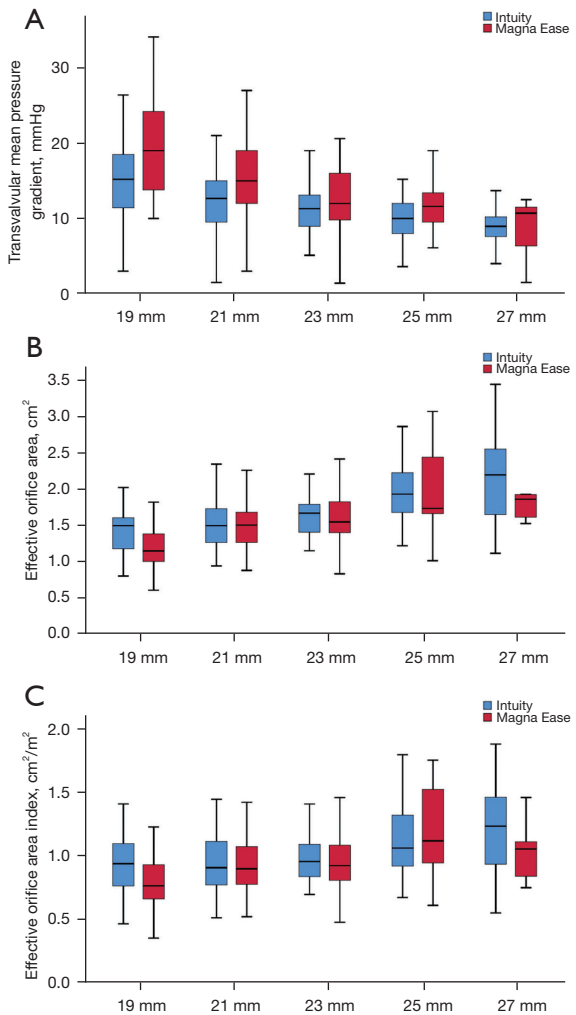

Figure 2 Comparison of the early hemodynamic performance between the valves stratified by prosthesis size. Comparison of (A) transvalvular mean pressure gradient, (B) effective orifice area, and (C) effective orifice area index.

suggested that RD valve demonstrated better hemodynamics than conventional bioprosthetic valves (4). Rahmanian and colleagues (5) similarly analyzed 163 patients who received either an Intuity valve or a PERIMOUNT Magna valve (Edwards Lifesciences, Irvine, CA, USA) with propensity score-matching, and showed lower transvalvular gradients and higher EOAI in the Intuity valve. The CADENCE-MIS (12), which enrolled minimally invasive RDAVR patients, also demonstrated that significantly lower peak gradients after 1 year, a trend toward lower mean gradients, and a significantly greater EOA compared with the control group were observed, but it compared the RD valve with a range of different conventional prostheses. Another previous study (13) comparing the Intuity valve with the PERIMOUNT Magna valve demonstrated a superior hemodynamics in the Intuity valve with significantly lower transprosthetic gradients, but it made comparisons for the whole population and for the combined data of the 21 and 23 mm valves as a subgroup analysis. A propensity-score matched study was performed to compare RDAVR from the TRITON cohort and conventional AVR from the Magna Ease postmarket study and it revealed that RDAVR patients showed significantly lower mean and peak gradients than conventional AVR patients (14).

In contrast to previous studies, this was the first study that directly compared the hemodynamics between the RD valve and its conventional counterpart as a control prosthesis in a size-by-size fashion. In addition, the assessment of hemodynamic performance by echocardiographic measurements could be affected by interobserver differences, and most of the previous multicenter studies might have this potential bias. However, since the present study was conducted on a single-center basis during a contemporary period, the comparison of echocardiographic measurements regarding valve hemodynamics would be more reliable than in other multicenter studies. The Intuity valve was introduced in our institution in 2016 and Magna Ease valve was also introduced around the same time. After introduction, both valves were steadily used during the period covered by this study.

Considering the identical valvular structures of the Magna Ease valve and its rapid-deployment successor, the subannular fixation components of Intuity valve may play an important role in the lowering transvalvular gradient. It is convincing that the subvalvular stent frame reshapes the LVOT, which consequently reduces turbulent flow and optimizes the hemodynamic performance of the bioprosthesis. Intuity valve is also free of the bulky pledget material, which is commonly used to fix the prosthesis in conventional valves, and induces turbulent flow and subclinical inflow obstruction (15,16). In an experimental investigation (17), an aortic root model was created using 3-dimensional printing, and the superior performance of the Intuity valve over Magna Ease valve was proven, showing that peak systolic flow across the Intuity valve was accompanied by a significantly lower maximum velocity, less turbulent shear stress, and less turbulent kinetic energy than flow across the Magna Ease valve. Another *in vitro* study (18) conducted using cadaveric human heart and micro-computed tomography revealed that the RD valve

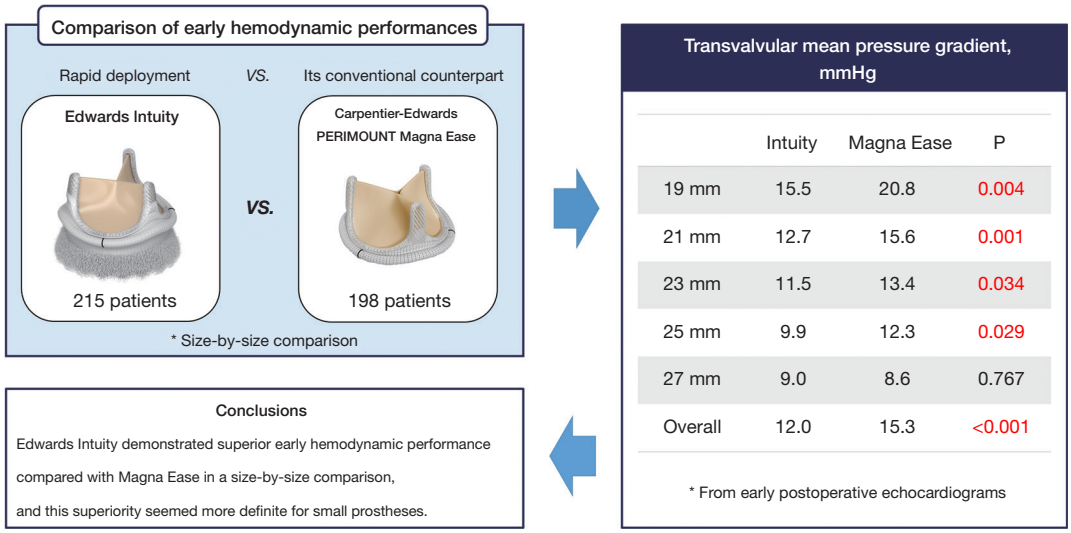

Figure 3 This study compared early hemodynamic performances between Edwards Intuity and Carpentier-Edwards PERIMOUNT Magna Ease valves. Intuity and Magna Ease valves were used in 215 and 198 patients, respectively, and valve hemodynamics were compared size-by-size. Transvalvular mean pressure gradients on early postoperative echocardiograms were significantly lower in Intuity valve than Magna Ease valve for 19, 21, 23, and 25 mm valves. In conclusion, Edwards Intuity demonstrated superior early hemodynamic performance compared with Magna Ease in a size-by-size comparison, and this superiority seemed more definite for small prostheses.

formed a larger and more circular LVOT than the control valve and demonstrated an increase in the LVOT hydraulic diameter, which was maintained consistently across the LVOT. The *in vivo* hemodynamic outcomes in our study are in good agreement with the results from these *in vitro* studies. Considering that subannular pledget placement is rarely performed in conventional AVR in our institution, it is certain that the subvalvular stent frame itself can produce a positive effect on valve hemodynamics. It should also be noted that although the superiority of Intuity valve is observed in patients with narrow LVOT, some patients require LVOT resection to relieve outflow obstruction and perform suitable AVR.

Although RDAVR has demonstrated promising clinical outcomes, conduction and the consequent requirement for permanent pacemaker implantation after RDAVR have been the Achilles' heel of the valve (19-21). The incidence of permanent pacemaker implantation has been reported to range from 5% to 15% (21-23). However, we previously reported an overall permanent pacemaker implantation rate of 1.8% (3 out of 167 patients) after RDAVR in our institution (9), which was similar to the outcomes after conventional AVR (1.5–3.9%) (21). This might be attributed to our procedure modification of using additional anchoring sutures and 5-mm videoscope to achieve 'complete annulus fitting'. Even in cases of aortic valves with elliptical opening, Intuity valve can be well-fixed and takes best advantage of our modified technique. Distorted geometry of native annulus was frequently observed, particularly in bicuspid aortic valves, and with additional anchoring sutures, the sewing ring of Intuity valve could be completely fitted to the native annulus (24). The skirt portion of Intuity valve also have advantages in reducing turbulent flow and optimizing the hemodynamic performance by reshaping the left ventricular outflow tract, particularly in patients with elliptical or distorted LVOT.

If the issue about the permanent pacemaker implantation after RDAVR can be overcome, Intuity valve can be the optimal choice of bioprosthesis for patients with a small aortic annulus to overcome prosthesis-patient mismatch after AVR. Ghoneim and colleagues (25) analyzed 4 choices to address the small aortic annulus (stented valve, stentless valve, sutureless valve, and root enlargement techniques), showing that stentless valves and the Trifecta prosthesis (St. Jude Medical, St. Paul, Minnesota, USA) produced the best hemodynamics in these cases. However, there are also reports about intraoperative malfunction (26) or early degeneration in cases of the Trifecta prosthesis because of leaflet dysfunction with calcification, fibrous thickening, or pannus formation (27,28). In the same study,

the Perceval sutureless valve (LivaNova, London, UK) showed comparable hemodynamics to conventional stented valves in patients with a small aortic annulus. Shrestha and colleagues (29) compared the hemodynamic performance of sutureless and conventional bioprostheses in geriatric patients with an annulus <22 mm, and there was no significant difference in terms of mean gradients and EOA between groups. Especially in these geriatric patients and small-sized aortic annuli, transcatheter aortic valve implantation (TAVI) should be considered a reasonable treatment option. Other techniques, including use of stentless valves, aortic root enlargement, complete aortic root replacement with homografts or a Ross procedure, would be more technically demanding and limited to a small subset of patient populations (30). In these circumstances, Intuity valve could be considered an alternative option to provide the best postoperative hemodynamics in small aortic roots.

Several shortcomings of Intuity valve reported in the previous studies should be recognized. The number of new postoperative conduction disorders, especially left bundle branch block, remains high during follow-up, although the long-term clinical significance was undetermined (31). There are also concerns that the existence of the subvalvular structure might cause anatomical changes in the aortic-mitral fibrous continuity, thus resulting in the alteration of mitral annular motion (32).

Limitations

There are several limitations that should be noted. First, this study was a retrospective single-center study with a small sample size although it would be advantageous to compare echocardiographic measurements of valve hemodynamics on a single-center basis. Second, the hemodynamic outcomes could be influenced by many factors, including body surface area, anemia, inflammation, and other medical conditions, but adjustments for these confounding factors were not performed in this study. The implantation technique of the Magna Ease valve, which varied among surgeons, might also confound the hemodynamic outcomes. Third, the present study only reported early hemodynamic profiles, whereas it has been recommended to evaluate the hemodynamic performance of AV prostheses at 6 months to 1 year after surgery (33-35). Also, data regarding the long-term durability beyond 5 years and incidence of structural valve deterioration, which would be of great importance, was not investigated. Follow-up investigation for any possible changes in valve hemodynamics beyond 1 year is needed. Fourth, all RDAVRs were performed with median sternotomy in this study, not like in other studies in which minimally invasive procedures were frequently used. The responsible surgeon put more value on lower incidence of paravalvular leakage and lower incidence of permanent pacemaker implantation by secure procedure with standard sternotomy than the advantages obtained by minimally invasive procedures.

Conclusions

Edwards Intuity demonstrated superior early hemodynamic performance compared with Magna Ease, and this superiority was more definite for small prostheses. This finding may help guide device selection in patients with small aortic roots.

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Footnote

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by Institutional Review Board of Seoul National University Hospital (No. H-2109-010-1251) and individual consent for this

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